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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,219	CIMBORA ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-160* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-160* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

10

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-4, drawn to an isolated protein complex comprising two proteins, said complex selected from the group consisting of: (i) a complex of a first protein and a second protein; (ii) a complex of a fragment of said first protein and a second protein; (iii) a complex of said first protein and a fragment of said second protein; and (iv) a complex of a fragment of said first protein and a fragment of said second protein, wherein, said first protein is LXR-alpha and said second protein is selected from the group consisting of utrophin, zyxin, LIMS1, PN7771, Homer-3, RACK1, EIF3S1, PSMD11, KIAA0610 and CIR; classified in class 530, subclass 350, 300.

Should Group 1 be elected, applicants are required to select one second protein from claim 1.

2. Claims 5 and 6, drawn to an antibody, immunoreactive of protein complex of claim 1; classified in class 530, subclass 350, 300, 387.1

Should Group 2 be elected, applicants are required to select one second protein from claim 1.

3. Claims 7-26, drawn to a method for diagnosing a physical disorder in an animal, comprising an assay for: steps (a) whether the protein complex of claim 1 present in tissue extract, (b) the ability of said proteins of claim 1to form protein complex, (c) and a mutation in a geneencoding a protein of said protein complex; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 3 be elected, applicants are required to select one second protein from claim 1.

4. Claims 27-29, 30, 31-37, 38, 39, drawn to a non human animal model for a physiological disorder wherein the genome of said animal has been modified such that the formation of a protein complex set forth in claim 1 has been altered; cell line obtained from said model; classified in class 536, subclass 23.1, 23.5; class 435, subclass, 325, 440.

Should Group 4 be elected, applicants are required to select one second protein from claim 1.

5. Claims 40-45, drawn to a composition comprising a first expression vector having a nucleic acid encoding a first protein or variants thereof; and a second expression vector having a nucleic acid encoding a second protein or variants thereof, wherein said proteins are the proteins of claim 1; vector; host cell; classified in class 536, subclass 23.1, 23.5; class 435, subclass, 69.1, 254.1, 320.1.

Should Group 5 be elected, applicants are required to select one second protein from claim 1.

6. Claims 46-50, 51, 52, drawn to a method for screening for drug candidates capable of modulating the interaction of the proteins of a protein complex by combining the proteins of said protein complex in the presence of a drug; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 6 be elected, applicants are required to select one second protein from claim 1.

7. Claims 53, 54, 55, drawn to a method for screening for drug candidates useful in treating a physiological disorder; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 7 be elected, applicants are required to select one second protein from claim 1.

8. Claims 56-58, drawn to a method for selecting modulators for a protein complex, contacting said protein complex with a test compound and determining the binding of said test compound to the protein; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 8 be elected, applicants are required to select one second protein from claim 1.

9. Claims 59-65, 66, 67, 84-88, drawn to a method for selecting modulators for an interaction between a first protein and a second protein, by contacting said first protein and a second protein in the presence of a test compound; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 9 be elected, applicants are required to select one second protein from claim 1.

10. Claims 68-70, drawn to a method for selecting modulators for a protein complex by contacting said protein complex with a test compound, determining the interaction between said first protein and second protein; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 10 be elected, applicants are required to select one second protein from claim 1.

11. Claims 71-74, drawn to a method for selecting modulators for an interaction between a first protein and a second protein by providing in a host cell a first fusion protein, a second fusion protein having, and a reporter gene; classified in class 530, subclass 350, 300; class 435, subclass 69.7, 7.21.

Should Group 11 be elected, applicants are required to select one second protein from claim 1.

12. Claims 75-77, drawn to a method for identifying a compound that binds to a protein in vitro; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 12 be elected, applicants are required to select one second protein from claim 1.

13. Claims 78-80, drawn to a method for selecting modulators for an interaction between a first protein and a second protein, comprising providing atomic coordinates, designing or selecting compounds for modulating; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 13 be elected, applicants are required to select one second protein from claim 1.

14. Claims 81-83, drawn to a method for providing inhibitors of an interaction between a first polypeptide and a second polypeptide, comprising providing atomic coordinates, designing or selecting compounds for modulating; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group 14 be elected, applicants are required to select one second protein from claim 1.

15. Claims 89-92, 93-95, 101, 102, 106-108, 109-112 drawn to a method for modulating in a cell having a first protein interacting with a second protein, administering to said cell a compound capable of modulating said protein complex, wherein said compound is a peptide; classified in class 530, subclass 350, 300; class 435, subclass 69.1, 7.21.

Should Group 15 be elected, applicants are required to select one second protein from claim 1, and items (a)-(f) from claim 90.

16. Claims 89-92, 93-95, 101, 102, 106-108, 109-112 drawn to a method for modulating in a cell having a first protein interacting with a second protein, administering to said cell a compound capable of modulating said protein complex, wherein said compound is an antibody; classified in class 530, subclass 350, 300, 387.1; class 435, subclass 69.1, 7.21.

Should Group 16 be elected, applicants are required to select one second protein from claim 1 and items (a)-(g) from claim 90.

17. Claims 89-92, 93-95, 101, 102, 106-108, 109-112 drawn to a method for modulating in a cell having a first protein interacting with a second protein, administering to said cell a compound capable of modulating said protein complex, wherein said compound is a nucleic acid; classified in class 536, subclass 23.1, 23.5, 24.5; class 435, subclass 69.1.

Should Group 17 be elected, applicants are required to select one second protein from claim 1 and items (a, b, h, i, j, k) of claim 90.

18. Claims 96 and 97, drawn to a method for modulating neuronal death in a patient, comprising modulating a protein complex, having a first protein interacting with a second protein; classified in class 530, subclass 300, 350; class 514, subclass 2.

Should Group 18 be elected, applicants are required to select one second protein from claim 1 and items (h, i, j, k) from claim 90.

19. Claims 98-100, 101, 102, 106-108, 109-112 drawn to a method for modulating neuronal death in a patient, comprising administering to the patient a compound capable of modulating a protein complex, having a first protein interacting with a second protein, wherein said compound is a peptide; classified in class 530, subclass 350, 300; class 435, subclass 69.1, 7.21.

Should Group 19 be elected, applicants are required to select one second protein from claim 1 and items (a)-(f) from claim 100.

20. Claims 98-100, 101, 102, 106-108, 109-112 drawn to a method for modulating neuronal death in a patient, comprising administering to the patient a compound capable of modulating a protein complex having a first protein interacting with a second protein, wherein said compound is an antibody; classified in class 530, subclass 350, 300, 387.1; class 435, subclass 69.1, 7.21.

Should Group 16 be elected, applicants are required to select one second protein from claim 1 and items (a)-(g) from claim 100.

21. Claims 98-100, 101, 102, 106-108, 109-112 drawn to a method for modulating neuronal death in a patient, comprising administering to the patient a compound capable of modulating a protein complex, having a first protein interacting with a second protein, wherein said compound is a nucleic acid; classified in class 536, subclass 23.1, 23.5, 24.5; class 435, subclass 69.1.

Should Group 21 be elected, applicants are required to select one second protein from claim 1 and items (h, i, j, k) from claim 100.

22. Claims 103-105, 106-108 and 109-112, drawn to a method for treating a physiological disorder comprising administering to a patient in need a compound capable of modulating a protein complex, having a first protein interacting with a second protein..., wherein said compound is a peptide; classified in class 530, subclass 350, 300; class 435, subclass 69.1, 7.21.

Should Group 22 be elected, applicants are required to select one second protein from claim 1 and items (a)-(f), (l) from claim 103.

23. Claims 98-100, 101, 102, 106-108, 109-112 drawn to a method for treating a physiological disorder comprising administering to a patient in need a compound capable of modulating a protein complex, having a first protein interacting with a second protein, wherein said compound is an antibody; classified in class 530, subclass 350, 300, 387.1; class 435, subclass 69.1, 7.21.

Should Group 23 be elected, applicants are required to select one second protein from claim 1 and items (a)-(g), (l) from claim 103.

24. Claims 98-100, 101, 102, 106-108, 109-112 drawn to a method for treating a physiological disorder comprising administering to a patient in need a compound

capable of modulating a protein complex, having a first protein interacting with a second protein, wherein said compound is a nucleic acid; classified in class 536, subclass 23.1, 23.5, 24.5; class 435, subclass 69.1.

Should Group 21 be elected, applicants are required to select one second protein from claim 1 and items (h, i, j, k, l) from claim 103.

25. Claims 109-112 drawn to a method for treating a physiological disorder comprising administering to a patient in need a compound capable of modulating the activity of a first protein or a second protein, wherein the activity is with a ligand; classified in class 530, subclass 350, 300; class 514, subclass 2, 44.

26. Claims 113-116 drawn to a method for modulating activity of a protein in a cell, said protein being first protein or a second protein, administering to said cell a compound capable of modulating said protein, wherein said compound is a peptide; classified in class 530, subclass 350, 300; class 435, subclass 69.1, 7.21.

Should Group 26 be elected, applicants are required to select one second protein from claim 1 and items (a)-(c) from claim 114.

27. Claims 113-116 drawn to a method for modulating in a cell having a first protein interacting with a second protein, administering to said cell a compound capable of modulating said protein complex, wherein said compound is an antibody; classified in class 530, subclass 350, 300, 387.1; class 435, subclass 69.1, 7.21.

Should Group 27 be elected, applicants are required to select one second protein from claim 1 and items (a) and (d) from claim 114.

28. Claims 113-116 drawn to a method for modulating in a cell having a first protein interacting with a second protein, administering to said cell a compound capable of modulating said protein complex, wherein said compound is a nucleic acid; classified in class 536, subclass 23.1, 23.5, 24.5; class 435, subclass 69.1.

Should Group 28 be elected, applicants are required to select one second protein from claim 1 and items (e) and (f) from claim 114.

29. Claims 117-144, 160 drawn to an isolated nucleic acid having a sequence of SEQ ID NO: 3 encoding a protein comprising an amino acid sequence of SEQ ID NO: 4, wherein said protein is capable of interacting with LXR-alpha; vector; host cell; microarray, method making protein; classified in class 435, subclass 69.1, 320.1, 252.3; class 536, subclass 23.1, 23.5.

30. Claims 145-154, 157-159 drawn to an isolated polypeptide having a sequence of SEQ ID NO: 4, wherein said protein is capable of interacting with LXR-alpha; microarray; classified in class 530, subclass 350, 300.

31. Claims 155 and 156 drawn to an antibody which is specifically immunoreactive with the polypeptide of SEQ ID NO: 4; classified in class 530, subclass 350, 300, 387.1.

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of invention 1 is related to the antibody of invention 2 as being the antigen for the antibody. Although the protein and antibody are related, they are distinct inventions. The protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify a receptor. Further, the protein of invention 1and the antibody of invention 2 are structurally and functionally distinct molecules with different amino acids and different sequences.

Invention 1 is related to inventions 3, 4, 6-16, 18, 19, 22, 23, 25, 26 and 30 as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of invention 1 has demonstrated different processes of use as set forth in the claims of inventions 3, 4, 6-16, 18, 19, 22, 23, 25, 26 and 30.

Inventions 1 and 5 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein product of Invention 1 can be made by another materially distinct processes, such as purification from the natural source or by chemical synthesis. Therefore, the inventions are distinct.

Inventions 1 and 17, 21, 24, 28, 29 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of invention 1 is not necessary for the practice of invention of 17, 21, 24, 28 and 29. Therefore the inventions are distinct.

Inventions 1 and 20, 27, 31 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of invention 1 is not necessary for the practice of invention of 20, 27 and 31. Therefore the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Mitra, Ph.D.
September 30, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER